

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/805,940	DEREGNAUCOURT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Frank I. Choi	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/7/2005.
2. ☒ The allowed claim(s) is/are 24-27[renumbered 1-4], 30-32[renumbered 5-7], 35[renumbered 8], 36[renumbered 9], 38-52[renumbered 10-24], 55-57[renumbered 25-27], 60[renumbered 28], 61[renumbered 29], 63-73[renumbered 30-40].
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 10/453,574.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>20050801, 20050713, 20040322</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material   | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

**EXAMINER'S AMENDMENT/REASONS FOR ALLOWANCE**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick Sage on 8/30/2005 and 8/31/2005.

The application has been amended as follows:

**Specification, Pg. 21, line 9:** delete "FIGURES" and insert in place thereof the following:

**-- BRIEF DESCRIPTION OF THE DRAWINGS --.**

**Claims 24, 45, lines 2,3 of each:** delete ", relative to administration of racemic milnacipran,".

**Claims 24, 49, line 10 of each:** after "enantiomer" but before the period mark insert the following:

--, wherein the administration of said mixture limits the risks of cardiovascular disturbances and/or the risks of organ and/or tissue toxicity, relative to administration of racemic milnacipran --.

**Claims 30, 31, 32, 55, 56, 57, line 1 of each:** after "wherein" delete "the".

**Claims 30, 31, 32, 55, 56, 57, line 2 of each:** after "and" but before "(1R,2S)" delete "the".

**Claims 38, 63, line 1 of each:** after "wherein" but before "phobia" insert the following:

-- the --.

**Claims 39, 64, line 1 of each:** after “wherein” but before “pain” insert the following:

-- the --.

**Claim 45, line 6:** after “hydrochloride salt, ” but before “and” insert the following:

-- wherein the administration of said mixture limits the risks of cardiovascular disturbances and/or the risks of organ and/or tissue toxicity, relative to administration of racemic milnacipran, --.

**Claims 47, 48, line 2 of each:** delete “, relative to administration of racemic milnacipran,“.

**Claims 47, 48, 70, 72, 73, line 8 of each:** after “hydrochloride salt, ” but before “and” insert the following:

-- wherein the administration of said mixture limits the risks of cardiovascular disturbances and/or the risks of organ and/or tissue toxicity, relative to administration of racemic milnacipran, --.

**Claim 49, lines 4,5:** delete “, relative to administration of racemic milnacipran,“.

**Claim 70, lines 3,4:** delete “, relative to administration of racemic milnacipran,“.

**Claims 72, 73, line 4 of each:** delete “, relative to administration of racemic milnacipran,“.

The drawings should be corrected as follows: Figure 1, clarify triangle points and graph line, Figures 3,4, identifiers to be translated from French to English, Figures 3, 4, clarify which bar refers to F2207 and F2695. In order to avoid abandonment of the application, applicant must make these drawing changes.

The following is an examiner's statement of reasons for allowance: In consideration of the Amendment (7/7/2005) and in reconsideration of the prior Office Actions and the responses thereto, the claimed invention is neither expressly disclosed nor fairly suggested by the prior art. The prior art does not disclose or make obvious the claimed invention in that the prior art does not expressly disclose the administration of a mixture of enantiomers of milnacipran which is substantially pure, which is defined in the Specification to mean "approximately 100% (1S,2R) enantiomers by weight" (Specification, Pg. 6, lines 29-31), in the (1S,2R) enantiomer and it is unexpected that by administering said mixture, as set forth in the claims, that the risks of cardiovascular disturbances and/or the risks of organ and/or tissue toxicity would be limited, relative to administration of racemic milnacipran (See Specification, Pg. 27, lines 5-31, Pgs. 28-49). Further, milnacipran is well known in the art to be used in the treatment of a wide variety of conditions or disorders which may be treated by double inhibition of serotonin and norepinephrine reuptake. See US Patent Application Publication Nos. 20050096395, 20050032782, 20040034101, 20030232805, 20030203055, 20030139476 and 20030130353, US Patent Nos. 6635675, 6184222, 6028070 and 5532244 and Foreign Application FR 2759290.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

November 28, 2005



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1617